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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/928,757	09/12/97	MAERTENS	G 1487-17

EXAMINER

HM12/0702

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ART UNIT	PAPER NUMBER
1643	6

ZEMAN, M

DATE MAILED: 07/02/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/1/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 49-56 is/are pending in the application.
Of the above, claim(s) 52+54 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 49-51, 53 + 55-56 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☒ received in Application No. (Series Code/Serial Number) 08/612,973.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Claims 49-56 are pending in this application.

2. Applicant's election with traverse of SEQ ID NO: 53 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search each and every peptide recited in the claims. This is not found persuasive because each peptide has a differing sequence, which may impart differing immunogenicity in a vaccine composition such that the immunogenicity of one peptide does not illuminate the immunogenicity of another peptide, as set forth in the election requirement.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 49-51, 53 and 55-56 read on the elected species. Claims 52 and 54 and all non-elected species are withdrawn from consideration as being drawn to a non-elected species with traverse in paper number 5.

Priority

4. This application is a divisional of Application Serial No. 08/612,973.

Drawings

5. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

6. Claims 49-51, 53 and 55-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The above rejected claims are drawn to prophylactic peptide vaccine compositions. To be a prophylactic vaccine, the vaccine must provide protective immunity, demonstrable by viral challenge experiments, in a reasonable model system. The specification, as filed, does not set forth that the claimed composition provides any sort of protective immunity in any model system which can be extrapolated to humans or higher mammals. While the skill in the art of virology is high, to date, no vaccines for HCV have provided any protective immunity, so that the expectation of success in this endeavor is not high (Farci et al. 1997). Farci et al states that HCV vaccines do not exist for HCV and would be highly unlikely to be efficacious, in view of the high reinfection rates. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of protective immunity the specification, as filed, is not enabling for such vaccines.

7. Claims 49-51, 53 and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the above rejected claims, the claimed composition is "obtainable by immunization of a mammal with a polypeptide". Does this mean Applicant is claiming a polypeptide composition, or some bodily fluid or extract from an immunized mammal? If the claimed composition is some extract from an immunized mammal, the claim fails to describe what such extract could be. If Applicant intends a polypeptide vaccine, the claims should be amended to that effect.

Claim 56, a method claim, improperly depends from claim 53, a product claim. It is assumed that claim 56 should depend from claim 55.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 49-51, 53 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bukh.

Bukh (US Patent 5,871,962) discloses E1 polypeptides from 51 separate isolates of HCV, including the isolate being claimed in the instant invention. (See Fig 2B1) Bukh characterizes these isolates as Type Ib. Bukh specifically discloses methods of making the polypeptides recombinantly, and methods of using the same polypeptides as immunogens or in vaccine compositions. Bukh discloses that both full length E1 polypeptides, and shorter polypeptides can be used as immunogens. Wile Bukh does not set forth the same N and C terminus of the polypeptide, the claims recite that the composition comprise at least the sequence recited, rendering the polypeptides of Bukh within the scope of the claims.

Taken together, the instant invention appears to be the same or slightly different from the prior art of selecting immunogenic E1 polypeptides for vaccine compositions.

One of ordinary skill in the art at the time the invention was made would have been motivated to select and evaluate the efficacy of E1 polypeptides as vaccines given the disclosure of Bukh indicating the suitability of E1 as an HCV vaccine. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie

obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Eisenschenk, can be reached on (703) 308-0452.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
June 29, 1999

Frank C. Eisenschenk
Supervisory Patent Examiner, Group 1600